No. 22-16770

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL GROCERS; CITIZENS FOR GMO LABELING; LABEL GMOS; RURAL VERMONT; GOOD EARTH NATURAL FOODS; PUGET CONSUMERS CO-OP; CENTER FOR FOOD SAFETY; NATIONAL ORGANIC COALITION,

Plaintiffs-Appellants,

v.

THOMAS VILSACK, Secretary of the United States Department of Agriculture; BRUCE SUMMERS, Administrator of the Agricultural Marketing Services; UNITED STATES DEPARTMENT OF AGRICULTURE,

Defendants-Appellees,

AMERICAN FARM BUREAU FEDERATION; UNITED STATES BEET SUGAR ASSOCIATION; AMERICAN SUGARBEET GROWERS ASSOCIATION,

Intervenor-Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of California

BRIEF FOR GOVERNMENT APPELLEES

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STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331, 1343, and 1346. 3-SER-139. The district court entered judgment on September 13, 2022. 1-SER-16; *see* 1-ER-2-26 (order and opinion). Plaintiffs filed a timely notice of appeal on November 10, 2022. 4-ER-877; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.[1]

STATEMENT OF THE ISSUES

In response to a patchwork of state laws related to the labeling of genetically modified foods, Congress amended the Agricultural Marketing Act of 1946 to direct the U.S. Department of Agriculture (USDA) to establish a national labeling standard for "bioengineered" foods. The statute defines the term "bioengineering, and any similar term, as determined by [USDA]" to refer to food that "contains" genetic

[1] The district court disposed of all issues in the case in the order granting summary judgment to plaintiffs in part and denying summary judgment to plaintiffs in part. 1-SER-16; *see* 1-ER-2-26. The order did not, however, state that it entered judgment for the government and intervenor-defendants on the claims where the court denied summary judgment to plaintiffs. Recognizing a question whether the court had, in fact, "adjudicat[ed] all the claims," Fed. R. Civ. P. 54(b), plaintiffs filed an unopposed motion in district court for an indicative ruling asking the court to clarify that it had entered judgment for the government and intervenors for the claims on which it denied summary judgment to plaintiffs. 1-SER-3-15. The district court denied the motion, stating that "the judgment provides total clarity on the disposition of the case." 1-SER-2. In light of that order and because the district court's opinion fully resolves the issues in the case, the government understands the district court to have issued a final judgment. *See Weston Family P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 618 (9th Cir. 2022) ("A decision is 'final' under § 1291 if it '(1) is a full adjudication of the issues, and (2) clearly evidences the judge's intention that it be the court's final act in the matter.'"); *see, e.g.*, *Riley's Am. Heritage Farms v. Elsasser*, 32 F.4th 707, 719 (9th Cir. 2022).

material with certain kinds of modifications. The statute provides that disclosures should be in the form of text, symbol, or electronic or digital link and that USDA should study whether consumers can access electronic disclosures and, if not, provide additional and comparable options. Following notice and comment, USDA promulgated a rule requiring disclosure of foods that contain certain kinds of modified genetic material. The rule requires that disclosures use the word "bioengineered," but regulated entities may add additional information or use additional terms.

This appeal presents the following questions:

1. Whether it was arbitrary and capricious or inconsistent with law for USDA to provide that regulated entities do not have to label food as bioengineered if they establish through scientifically-validated means that the food does not contain modified genetic material.
2. Whether it was arbitrary and capricious or inconsistent with law to require bioengineered food disclosures to use the term "bioengineered."
3. Whether, following the district court's conclusion that USDA improperly permitted disclosures by text message, the district court abused its discretion by remanding the matter to the agency rather than vacating the text-message option.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory Background

In 2016, States and local governments began imposing varied labeling requirements for foods that contain or even might contain genetically modified ingredients. S. Rep. No. 114-403, at 1-2 (2016) (Senate Report); *see* H.R. Rep. No. 114-208, pt. 1, at 11-12 (2015) (discussing state proposals that "would produce a state-by-state patchwork of laws that lead to misinformation and confusion for consumers as well as costly disruptions to the food supply chain"). Congress sought to address the "state-by-state patchwork of regulations" by "preempt[ing] state and local actions that mandate labeling of whether a food or seed is genetically engineered." Senate Report 1.

Congress accordingly amended the Agricultural Marketing Act of 1946 to address "any claim in a disclosure that a food bears that indicates that the food is a bioengineered food." 7 U.S.C. § 1639a(a). The statute thus directs USDA to "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered" and to "establish such requirements and procedures as the Secretary determines necessary to carry out the standard." *Id.* § 1639b(a). The statute defines the term "bioengineering" and "any similar term, as determined by the Secretary" as referring to a food "(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature." *Id.* § 1639(1). The statute

makes clear that "[a] food may bear a disclosure that the food is bioengineered only in accordance with [USDA] regulations." *Id.* § 1639b(b)(1). The statute also displaces any conflicting state or local rule "relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering," *id.* § 1639b(e), and any state or local rule "relating to the labeling of whether a food . . . is genetically engineered . . . or was developed or produced using genetic engineering," *id.* § 1639i(b).

The statute establishes certain requirements for the national rule to be established by USDA. 7 U.S.C. § 1639b(b)(2). Among other things, USDA must "determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food." *Id.* § 1639b(b)(2)(B); *see also, e.g.*, *id.* § 1639b(b)(2)(A) (stating that the regulations should not consider animal-derived food to be bioengineered "solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance"). USDA must "require that the form of a food disclosure . . . be a text, symbol, or electronic or digital link . . . with the disclosure option to be selected by the food manufacturer." *Id.* § 1639b(b)(2)(D); *see id.* § 1639b(d). USDA must also "conduct a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods." *Id.* § 1639b(c)(1). If the Secretary determines, after reviewing the results of the study, "that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods," then

USDA must "provide additional and comparable options to access the bioengineering disclosure." *Id.* § 1639b(c)(4).

B. Regulatory Background

1. In 2017, USDA sought public input on various questions related to establishing a national bioengineered food standard. 83 Fed. Reg. 19,860, 19,860 (May 4, 2018) (3-SER-82); *see* 3-SER-112-120. These included questions about the scope of the rule, including what sorts of genetic modifications render a food bioengineered, 3-SER-112-113; whether the agency should require disclosure for foods that contain highly refined ingredients, such as oils or sugars, that are "derived from bioengineered crops" but contain no detectable modified genetic material "such that they are indistinguishable from their non-engineered counterparts," 3-SER-113; and what amount of bioengineered substance in a food should require the food to be disclosed as bioengineered, 3-SER-114. These also included questions about the nature of the disclosure, such as what terms, text, and symbols could be used on a disclosure, 3-SER-112; 3-SER-115, and what sorts of electronic disclosures to permit, 3-SER-115-116; 3-SER-118. USDA received over 112,000 responses. 83 Fed. Reg. at 19,860 (3-SER-82).

2. In May 2018, USDA issued a Notice of Proposed Rulemaking (NPRM) for a bioengineered food disclosure standard. 83 Fed. Reg. at 19,860-19,889 (3-SER-82-111). With certain exceptions, the proposed rule defined a "bioengineered food" as "a food that contains genetic material that has been modified through *in vitro* recombinant

deoxyribonucleic acid (DNA) techniques" where "the modification could not otherwise be obtained through conventional breeding or found in nature." *Id.* at 19,885 (3-SER-107). The proposed rule carved out "[a]n incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food." *Id.*; *see also id.* at 19,886 (3-SER-108) (exempting from disclosure, *inter alia*, foods served in restaurants, very small food manufacturers, and foods in which an ingredient contains a bioengineered substance that is inadvertent or technically unavoidable and comprises a small amount of the food).

USDA discussed and proposed options for addressing foods that contain certain highly refined ingredients. 83 Fed. Reg. at 19,885-19,886 (3-SER-107-108); *see id.* at 19,862-19,863 (3-SER-84-85). USDA explained that, by statute, the term "bioengineering" "refer[s] to a food" that "contains" certain modified "genetic material." *Id.* at 19,862 (3-SER-84) (quoting 7 U.S.C. § 1639(1)). USDA noted that comments submitted in advance of the NPRM had taken divergent views on how the agency should apply that definition to "highly refined foods and ingredients," such as sugars and oils that are derived from genetically modified plants but may contain no modified genetic material. *Id.* Some commenters urged that such foods "have undergone processes that have removed genetic material such that it cannot be detected" and therefore do not contain genetic material as required by the statute or contain "incidental or trace amounts" that USDA should decline to capture in the regulatory definition. *Id.* at 19,862-19,863 (3-SER-84-84). Other commenters urged

that "the definition of 'bioengineering' includes all foods produced from bioengineering" because even a highly refined product, such as sucrose created from a bioengineered sugar beet, "contains modified genetic material before it is processed," "one could suppose the resulting product (sugar) would contain at least some trace amount of genetic material," and testing might not detect trace amounts. *Id.* at 19,863 (3-SER-85). USDA specifically invited further comment on this issue. *Id.*

The proposed rule also addressed the content and form of the required disclosures. 83 Fed. Reg. at 19,886-19,989 (3-SER-108-111); *see id.* at 19, 869-19,877 (3-SER-91-99). USDA proposed that disclosures would use the word "bioengineered," such as by stating that a food is a "bioengineered food" or "contains a bioengineered food ingredient." *Id.* at 19,886-19,887 (3-SER-108-109). The agency explained that it was proposing the term "bioengineered," which echoes the statute's terminology, rather than "alternative phrases, such as 'genetically modified' or 'genetically engineered'" because the "statutory term, 'bioengineering,' adequately describes food products of the technology that Congress intended to be within the scope of the [standard]." *Id.* at 19,871 (3-SER-93). USDA also solicited comments on whether, if the Secretary determined that consumers would have difficulty accessing the electronic disclosure, the agency should add a text-message disclosure option. *Id.* at 19,875-19,876 (3-SER-97-98).

3. USDA received approximately 14,000 comments. 83 Fed. Reg. 65,814, 65,814 (Dec. 21, 2018) (2-SER-18); *see id.* at 65,832-65,866 (2-SER-36-70) (describing and

responding to comments). As particularly relevant here, commenters divided on how to approach foods that contain highly refined ingredients that are produced from genetically modified plants but do not contain detectable genetic material from those plants. *See id.* at 65,833-65,837 (2-SER-37-41). Some commenters stated that such highly refined foods do not contain modified DNA and thus "do not meet the statutory definition of 'bioengineering,'" which refers to food that "contains genetic material." *Id.* at 65,833 (2-SER-37) (quoting 7 U.S.C. § 1639(1)). Some of those commenters stressed that "the proposed regulation governs the food product, not the source plant." *Id.* Many of those commenters "cited several scientific studies they viewed as demonstrating an absence of genetic material in such foods." *Id.* Other commenters urged that USDA should require "labeling of all foods produced through bioengineering" and that "processed foods originating from [bioengineered] raw agricultural commodities should be considered bioengineered food, regardless of whether modified genetic material remains detectable." *Id.* at 65,834 (2-SER-38). Some of these commenters "did not believe disclosure should rely only on the detection of genetic material" and "noted that scientific methods may advance" and one day be able to detect material that is undetectable today. *Id.* These commenters "cited several studies documenting the evolution of our ability to detect previously undetectable bioengineered products." *Id.*

Commenters also divided on what terms should be used in the disclosure of bioengineered foods. Some suggested that the term "bioengineered" may be

"misleading or confusing" and that terms such as "genetically modified organism," "GMO," or "genetic engineering" are preferable. 83 Fed. Reg. at 65,851, 65,852 (2-SER-55; 2-SER-56). Others suggested that regulated entities be permitted to use those terms "in additional voluntary statements and symbols." *Id.* at 65,858 (2-SER-62). And others raised questions whether USDA "should consider" those alternate terms "synonymous and interchangeable with 'bioengineered.'" *Id.*

4. In December 2018, USDA issued a Final Rule. 83 Fed. Reg. 65,814-65,876 (2-SER-18-80) (codified at 7 C.F.R. pt. 66). The Final Rule generally defines a "bioengineered food" as "[a] food that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature." 7 C.F.R. § 66.1. The Final Rule provides that "[s]uch a food does not contain modified genetic material if the genetic material is not detectable" pursuant to the rule's provisions governing detectability. *Id.* Those provisions state that a regulated entity can establish that a food is not bioengineered in one of three ways: (1) maintaining records "to verify that the food is sourced from a non-bioengineered crop or source"; (2) maintaining records "to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable"; or (3) maintaining "[c]ertificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material." *Id.* § 66.9(a). USDA noted that it had adopted a "definition of 'bioengineered food'

that hews closely to the plain language of the amended Act" by providing that if a food does not contain modified genetic material, it is not a bioengineered food. 83 Fed. Reg. at 65,816 (2-SER-20).[2]

USDA additionally established the List of Bioengineered Foods, which is a list of "foods for which bioengineered versions have been developed," and USDA required that the list be reviewed annually. 7 C.F.R. §§ 66.1, 66.6, 66.7; *see* 83 Fed. Reg. at 65,818-65,820, 65,838-65,841 (2-SER-22-24; 2-SER-42-45).[3] Foods that are on the List or contain ingredients produced from items on the List are presumed to be bioengineered unless the regulated entity establishes otherwise through the three means set out in the rules. 83 Fed. Reg. at 65,826-65,827, 65,852; 65,864 (2-SER-30-31; 2-SER-56; 2-SER-68); *see* 7 C.F.R. §§ 66.6, 66.7, 66.9, 66.100(b), 66.102(a), 66.104(b).[4]

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[2] The definition also excludes "[a]n incidental additive . . . at an insignificant level and that does not have any technical or functional effect in the food." 7 C.F.R. § 66.1. And the Final Rule also excludes foods served in restaurants, very small food manufacturers, foods where "no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient," animal-derived foods based solely on animals having consumed bioengineered feed, and foods certified under a separate program for organic foods. *Id.* § 66.5(a).

[3] The current list comprises "Alfalfa, apple (Arctic TM varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer, coat protein-mediated virus-resistant varieties), sugarbeet, and sugarcane (Bt insect-resistant varieties)." 7 C.F.R. § 66.6.

[4] The government notes that the provision regarding a text disclosure refers to cases in which "records maintained by a regulated entity demonstrate that the food is bioengineered," while the provision regarding a symbol disclosure refers to cases in

Continued on next page.

USDA addressed comments urging that "processed foods originating from [bioengineered] raw agricultural commodities should be considered bioengineered food, regardless of whether modified genetic material remains detectable in the final product." 83 Fed. Reg. at 65,834 (2-SER-38). USDA explained that "the statutory definition of 'bioengineering'" covers food that "contain[s]" certain modified "genetic material" and that USDA therefore "will not require disclosure for refined products that do not contain modified genetic material." *Id.* The agency recognized that it had authority to require disclosure where a food may contain modified genetic material even if its presence has not been ascertained. Accordingly, USDA placed the burden on regulated entities to establish that foods for which bioengineered versions have been developed do not contain genetically modified material through the rules just discussed. *Id.* at 65,816-65,817, 65,833-65,837 (2-SER-20-21; 2-SER-37-41).

The Final Rule requires that the term "bioengineered" appear in the bioengineered food disclosure. *See* 7 C.F.R. §§ 66.102(a), 66.104(a), 66.106(b), 66.108(b). The agency explained that the statute "sets forth use of the term bioengineering" and that requiring the term "bioengineered" rather than some set of

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which "records maintained by a regulated entity demonstrate that the food is bioengineered, or do not demonstrate whether the food is bioengineered." 7 C.F.R. § 66.102(a), 66.104(b). The difference in wording was apparently inadvertent and not intended to establish different criteria among the forms of disclosure, all of which are generally available to a regulated entity. *See id.* § 66.100(b). USDA is examining this issue to determine whether a technical amendment to avoid any confusion may be warranted.

alternative options serves to "ensur[e] disclosure consistency" and minimize "confusion." 83 Fed. Reg. at 65,851 (2-SER-55). Among other things, "the language used by Congress in the amended Act clearly and accurately describes the technology" captured by the statutory definition of "bioengineering." *Id.* at 65,852 (2-SER-56). USDA made clear that it has the statutory authority to use "other terms that are similar to 'bioengineering,'" *id.* at 65,851 (2-SER-55), and that it "considered similar terms to bioengineering as permitted by the amended Act," *id.* at 65,837 (2-SER-41). But the agency "ultimately determined that bioengineering and bioengineered food accurately reflected the scope of disclosure and the products and potential technology at issue." *Id.* The agency "believe[d] that using other terms such as genetic engineering or genetically modified organisms" may "muddy the scope of disclosure" or "create inconsistencies" with the statute's preemption provisions, which use both sets of terms. *Id.* The agency confirmed that "nothing in the final rule prohibits regulated entities from providing additional statements or other claims regarding bioengineered foods and bioengineered food ingredients, so long as such statements are consistent with all other applicable laws and regulations." *Id.* at 65,852 (2-SER-56); *see* 7 C.F.R. § 66.118; *see also* 83 Fed. Reg. at 65,858-65,859 (2-SER-62-63).

With respect to covered, bioengineered foods, the Final Rule generally requires those foods to "bear a disclosure indicating that the food is a bioengineered food or contains a bioengineered food ingredient." 7 C.F.R. § 66.3(a)(1); *see id.* § 66.5 (exemptions); *id.* § 66.100 (general rule for disclosure). Regulated entities must make

mandatory disclosures through at least one of several methods of indicating that the food is a bioengineered food: a text statement that the food is a "Bioengineered food" or "Contains a bioengineered food ingredient," *id.* § 66.102; a specific circular symbol that includes the word "BIOENGINEERED," *id.* § 66.104; an electronic link and phone number accompanied by a direction to scan the link or call the number "for more food information" that leads to a product page or audio message containing the text or symbol disclosure, *id.* § 66.106; or a message to "Text [command word] to [number] for bioengineered food information" that yields a response comprising the text disclosure, *id.* § 66.108. Regulated entities can choose to provide additional information regarding bioengineered foods, such as which ingredient is bioengineered, and can make additional statements or use additional terms like "GMO." *See id.* § 66.118. The rule also permits voluntary disclosures by entities that are otherwise exempt from the disclosure requirements and for certain foods that do not meet the definition of "bioengineered food" but are derived from bioengineered crops or other sources. *See id.* § 66.116.

The Secretary, upon reviewing the statutorily mandated study, "determined that consumers would not have sufficient access to the bioengineering disclosure through electronic or digital means under ordinary shopping conditions at this time." 83 Fed. Reg. at 65,828 (2-SER-32). "While a large number of Americans have a smartphone and a large number of national and regional supermarkets provide Wi-Fi, most consumers in the study experienced technical challenges in accessing the bioengineered

food disclosure on their phones." *Id.*; *see id.* at 65,855 (2-SER-59). USDA thus added the "text message" disclosure as an "additional and comparable" disclosure option, whereby consumers could simply send a text message and receive a written disclosure. *Id.* at 65,828-65,829 (2-SER-32-33); *see* 7 C.F.R. § 66.108.

C. Prior Proceedings

1. Plaintiffs are four non-profit organizations that advocate for labeling and regulation of genetically modified foods, 3-SER-140-143; three grocers that sell organic foods and are interested in labeling of genetically modified foods, 3-SER-143-145; and a national coalition of groups involved in organic food production, 3-SER-145.

In July 2020, roughly 17 months after USDA promulgated the Final Rule, plaintiffs filed suit challenging the USDA requirements for labeling of bioengineered food. *See* 4-ER-885. Plaintiffs brought six claims. They contended (1) because USDA's study found that many consumers have difficulty accessing electronic disclosures, it was arbitrary and capricious to give regulated entities the option to provide disclosure solely through electronic or digital link or via a text message, 3-SER-159-182; (2) USDA erred by requiring what the statute calls "bioengineered" foods to be labeled as "bioengineered" rather than authorizing terms such as "genetically modified," "genetically engineered," "GE foods," or "GMOs," 3-SER-182-202; (3) the Final Rule was inconsistent with the statute because the rule does not apply to highly refined foods that contain no detectable modified genetic material, 3-SER-203-220; (4) requiring particular disclosures violates the First Amendment freedom of speech, 3-SER-220-

232; (5) the preemption of certain state and local laws violates the Tenth Amendment, 3-SER-232-241; and (6) various provisions of the rule are void for vagueness in violation of the Fifth Amendment, 3-SER-241-249.

2. The government filed the administrative record, and the district court granted plaintiffs' motion for summary judgment in part and denied it in part. The court first considered plaintiffs' challenge "to the USDA's decision to provide a text-message disclosure option" and held that USDA's decision to offer a text-message disclosure option was arbitrary and capricious. 1-ER-16-21. Ordinarily, the USDA regulations must permit regulated entities to disclose that a food is bioengineered through "text, symbol, or electronic or digital link." 7 U.S.C. § 1639b(b)(2)(D). But because the Secretary, upon reviewing the results of the statutorily-mandated study, determined that consumers would not have sufficient access to an electronic or digital disclosure, USDA was required to "provide additional and comparable options to access the bioengineering disclosure." *Id.* § 1639b(c)(4). The court stated that although a text-message option is "additional and comparable," USDA could not simply "provide[] a fourth disclosure option that regulated entities can select instead of the electronic disclosure method." 1-ER-17-18 (emphasis omitted). A "separate text message disclosure option," the court reasoned, "did nothing to fix the problem of inaccessible electronic disclosures." 1-ER-18. The court added that doing so exceeded the agency's statutory authority by "expand[ing] the disclosure options for manufacturers beyond the 'text, symbol, or electronic or digital link' choices." 1-ER-19 (quoting 7 U.S.C.

§ 1639b(b)(2)(D)). "Consequently," the court held, USDA's "decision to implement a standalone text message disclosure option was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" 1-ER-20 (quoting 5 U.S.C. § 706(2)(A)).

The court remanded the matter to USDA but declined to vacate the text-message disclosure option. 1-ER-20-21. The district court explained that under this Court's cases, "[w]hether remand without vacatur is appropriate 'depends on how serious the agency's errors are and the disruptive consequences of an interim change that may itself be changed.'" 1-ER-20 (quoting *California Cmtys. Against Toxics v. U.S. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (per curiam)). The district court believed that "[t]he text message disclosure decision was a significant error" but concluded that "legitimate and persuasive" concerns about disruption counseled against vacatur. 1-ER-21. The court thus agreed with the government that vacating the text-message option "would disrupt consumer access to bioengineering disclosures" and "would disrupt the food industry, which was required to comply with the regulations as of January 1, 2022." 1-ER-21.

The court denied summary judgment to plaintiffs on their remaining claims. The court held that USDA had ample basis to require that disclosures of what the statute calls "bioengineered" foods use the word "bioengineered" rather than "terms like GE and GMO." 1-ER-21-22. The court rejected plaintiffs' argument that the statute "require[d]" USDA to use other terms. 1-ER-21-22. The court also explained that USDA had considered whether to use other terms but determined that those terms

could "blur the scope of the regulations, and lead to inconsistent disclosures." 1-ER-22 (citing 83 Fed. Reg. at 65,837, 65,851 (2-SER-41; 2-SER-55)).

The court also rejected plaintiffs' claim that the labeling requirement must apply to all foods derived from bioengineered raw agricultural sources regardless of whether the foods contain any detectable modified genetic material. 1-ER-22-23. The court noted USDA's conclusion, "based on multiple studies, that 'for many refined food products and ingredients, the refining process removes the genetic material so that it can no longer be detected.'" 1-ER-23. The court also observed that in issuing the Final Rule, USDA considered and specifically sought comment on whether to require labeling of all highly refined foods, even if they have no "detectable levels of modified genetic material." 1-ER-8. USDA ultimately "defined bioengineering" to exclude foods with no detectable genetically modified material. 1-ER-8.

But USDA also created a "safety net" by establishing a "List of Bioengineered Foods" that are "presumed to be bioengineered" and then "updating the list" annually. 1-ER-8-9 (quoting 7 C.F.R. § 66.6 and then citing 7 C.F.R. § 66.7). "A highly refined food produced with a listed item as an ingredient is presumed to require disclosure, and would be exempted only if the regulated entity proved that the product is not bioengineered." 1-ER-9; *accord* 1-ER-22. That framework, the court explained, "err[s] on the side of disclosure" with respect to "food that could be bioengineered." 1-ER-22 (quoting 83 Fed. Reg. at 65,826 (2-SER-30)). The court also noted that "[t]he statute expressly states that the agency 'shall' promulgate regulations that 'determine the

amounts of a bioengineered substance that may be present in a food, as appropriate, in order for the food to be a bioengineered food.'" 1-ER-23 (quoting 7 U.S.C. § 1639b(b)(2)(B)). In response to plaintiffs' supposition that "future testing methods" might be able to detect modified genetic material that cannot be detected today, the court explained that USDA was not obligated to cover any food that could conceivably contain such material. 1-ER-23. The court also made clear that USDA "did not ignore" the possibility of progress, insofar as the agency required annual reviews of the list of presumptively bioengineered ingredients. 1-ER-23.[5]

SUMMARY OF ARGUMENT

I. USDA is entrusted with establishing a single, national standard to govern disclosure of bioengineered foods. 7 U.S.C. §§ 1639a(a), 1639b. USDA reasonably exercised its discretion.

A. In response to a state-by-state patchwork of regulations, Congress amended the Agricultural Marketing Act in 2016 to address "any claim in a disclosure that a food bears that indicated that the food is a bioengineered food." 7 U.S.C. § 1639a(a). The statute defines "[t]he term 'bioengineering', and any similar term, as determined by the Secretary" as "refer[ing] to a food . . . that contains" certain modified "genetic material." *Id.* § 1639(1). And it directs USDA to "establish a national mandatory

[5] The court also held that plaintiffs lack standing to bring their First and Fifth Amendment claims, 1-ER-13-16, and that plaintiffs' Tenth Amendment claim fails on the merits, 1-ER-23-26. Plaintiffs have not renewed those claims on appeal.

bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered" and to "establish such requirements and procedures as the Secretary determines necessary to carry out the standard." *Id.* § 1639b(a).

Consistent with the statutory definition, USDA made the disclosure requirements applicable to foods that contain the relevant kind of modified genetic material. USDA also established three logical and validated means that regulated entities can employ to establish that foods do not contain modified genetic material. USDA recognized that the statute does not require the agency to establish with certainty that a product contains modified genetic material in order to make it subject to the disclosure requirements. Accordingly, the Final Rule provides that USDA will publish and update a list of foods for which bioengineered versions have been developed. And the rule places the onus on regulated entities to rebut the presumption that foods on that list or containing ingredients produced from items on the list contain modified genetic material.

Plaintiffs are quite wrong to insist that the statute requires a bioengineered food disclosure for any food that was made by using a bioengineered, raw agricultural commodity even when scientifically-validated evidence establishes that the food does not contain modified genetic material. Congress could have—but did not—adopt such a definition, and the statutory definition turns on whether a food, in fact, "contains" certain modified genetic material. The statute's history confirms this understanding of the statutory terms, which reflect compromises in a hard-fought legislative process.

Plaintiffs reframe many of the same arguments as contentions that USDA acted arbitrarily and capriciously in its evaluation of the available data or should have reached a different balance between competing preferences and policy considerations. In making those arguments, plaintiffs disregard the nature of arbitrary and capricious review, as well as the agency's reasoned explanations. Plaintiffs' arguments largely reduce to the contention that scientifically-validated means of determining whether a food contains modified genetic material cannot be trusted. But plaintiffs provide no sound reason to believe that USDA acted unreasonably in concluding otherwise.

B. Plaintiffs are on no firmer footing when they challenge the requirement that bioengineered food disclosures use the term "bioengineered" rather than some different term or menu of terms, such as "genetically engineered" or "genetically modified." The statute uses the term "bioengineered" throughout and gives "[t]he term 'bioengineering', and any similar term, as determined by the Secretary," a very specific meaning. 7 U.S.C. § 1639(1). It refers only to foods that contain genetic material modified in certain ways and where those modifications could not be obtained by conventional breeding or found in nature. *Id.* The agency reasonably explained that the term "bioengineered" thus captures the specific technology and products at issue, whereas other terms, which have varied meanings in colloquial use and in other state and federal regimes, could muddy the understanding of the bioengineered foods disclosure. That various agencies and Members of Congress have used other terms in

other contexts or even considered other terms for this disclosure regime casts no doubt on the reasonableness of USDA's determination.

II. After holding that USDA erred by creating a text-message disclosure option, the district court remanded the matter to the agency without vacatur. The court properly applied this Court's decisions and did not abuse its discretion in concluding that the disruptive consequences of vacating the text-message option counseled in favor of leaving that option in place pending further administrative proceedings. Plaintiffs' contentions that the district court failed to engage in the proper equitable balancing misread the court's decision. And plaintiffs' passing suggestions that vacatur is unlikely to be disruptive fare no better. Plaintiffs seems to assume that once the district court invalidated the text-message option, it would have then "vacated" both the text-message option and the electronic disclosure option. But invalidating the severable text-message option does not invalidate the separate electronic option. And, in all events, plaintiffs' newfound proposal to "vacate"—really to enjoin—both the text-message and electronic disclosure options would also have been highly disruptive.

STANDARD OF REVIEW

I. This Court reviews a district court's grant of summary judgment de novo. *Friends of Animals v. U.S. Fish & Wildlife Serv.*, 28 F.4th 19, 28 (9th Cir. 2022). Agency actions are reviewed under the Administrative Procedure Act (APA) and will only be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Solar Energy Indus. Ass'n v. Federal Energy Regulatory Comm'n*,

80 F.4th 956, 978 (9th Cir. 2023) (quoting 5 U.S.C. § 706(2)(A)). Under that standard, a court reviews whether the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). This form of review is "highly deferential and presumes that the agency action is valid if a reasonable basis exists for the agency's decision." *Friends of Animals*, 28 F.4th at 28 (quotation marks omitted).

II. This Court reviews a district court's decision to remand without vacatur for abuse of discretion. *Western Watersheds Project v. McCullough*, No. 23-15259, 2023 WL 4557742, at *3 (9th Cir. July 17, 2023); *see Pit River Tribe v. U.S. Forest Serv.*, 615 F.3d 1069, 1080 (9th Cir. 2010) ("We review for an abuse of discretion the district court's equitable orders."); *see also, e.g.*, *California Cmtys. Against Toxics v. U.S. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (per curiam) (remand without vacatur is an equitable determination).

ARGUMENT

I. The Final Rule Is Supported By Substantial Evidence And Well Within USDA's Discretion

The U.S. Department of Agriculture is entrusted with establishing a single, national standard to govern disclosure of bioengineered foods. 7 U.S.C. §§ 1639a(a), 1639b. USDA reasonably exercised that discretion in promulgating the bioengineered food disclosure standard. Plaintiffs' contrary arguments fail to grapple with the agency's

detailed explanations and fundamentally misunderstand the governing statute and the standard of review for administrative actions.

A. USDA Reasonably Required Food Labels To Disclose That Foods Are Bioengineered Only If The Foods Contain Detectable Modified Genetic Material

1. In response to a "state-by-state patchwork of regulations," Senate Report 1, Congress amended the Agricultural Marketing Act of 1946 to address "any claim in a disclosure that a food bears that indicates that the food is a bioengineered food," 7 U.S.C. § 1639a(a). The statute defines "[t]he term 'bioengineering', and any similar term, as determined by the Secretary" as "refer[ring] to a food . . . that contains" certain modified "genetic material." *Id.* § 1639(1). And it directs USDA to "establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered" and to "establish such requirements and procedures as the Secretary determines necessary to carry out the standard." *Id.* § 1639b(a).

USDA promulgated a "definition of 'bioengineered food' that hews closely to the plain language of the amended Act." 83 Fed. Reg. at 65,816 (2-SER-20). Consistent with the statutory definition, USDA defined a "bioengineered food" as "[a] food that contains" certain modified "genetic material," 7 C.F.R. §§ 66.1, 66.3(a), noting that "[f]oods with no modified genetic material are not bioengineered food and therefore are not subject to [bioengineered] disclosure," 83 Fed. Reg. at 65,836 (2-SER-40); *see, e.g.*, *id* at 65,864 (2-SER-68) (explaining that if "a food or ingredient does not contain

modified genetic material," it "would not be required to disclose the food or ingredient as [bioengineered]"); *see also id.* at 65,833, 65,834, 65,835, 65,839, 65,844, 65,845, 65,859, 65,864, 65,868 (2-SER-37; 2-SER-38; 2-SER-39; 2-SER-43; 2-SER-48; 2-SER-49; 2-SER-63; 2-SER-68; 2-SER-72) (similar).

The statute does not require USDA to establish with certainty that a product contains modified genetic material in order to make it subject to the disclosure requirements. Accordingly, in order to avoid those requirements, regulated entities must "maintain records that substantiate their claim that the products do not contain modified genetic material." 83 Fed. Reg. at 65,834 (2-SER-38); *see id.* at 65,843, 65,859 (2-SER-47; 2-SER-63). To substantiate that claim, records must "verify that the food is sourced from a non-bioengineered crop or source," "verify that the food" is produced with a "refinement process" that has been "validated" as producing a final product without any detectable modified genetic material, or document "analysis" or other "testing" that is "appropriate to the specific food" and "confirm[s] the absence of modified genetic material." 7 C.F.R. § 66.9(a).

USDA explained that it had determined to require labeling of food based on whether the food itself contains certain modified genetic material rather than to assume that food contains genetically modified material whenever genetically modified material was used in processing. *See* 83 Fed. Reg. at 65,816 (2-SER-20) (noting comments urging that the agency should automatically require disclosure of "all foods produced from bioengineering," whether or not the genetic material was detectable in the food itself);

see also id. at 65,816-65,817, 65,833-65,834 (2-SER-20-21; 2-SER-37-38). In declining automatically to require disclosure of ingredients that are produced from bioengineered crops, USDA explained that certain types of processing "degrade" and "eliminate DNA," and USDA noted that the "International Organization for Standardization" had already "developed numerous validated sampling and detection methods to detect rDNA in food products." *Id.* at 65,833-65,834 (2-SER-37-38).

USDA discussed various studies of whether highly refined foods contain DNA from the raw agricultural commodities used to create them. One study, for example, "attempted to extract DNA from 55 common foodstuffs derived from soybean, corn, potato, rice, sugar beet, tomato and wheat." 83 Fed. Reg. at 65,833 (2-SER-37). Although plant DNA was present in "most of the foodstuffs," scientists were "not able to extract any DNA from refined sugar and oil." *Id.* Another study "analyzed 100 foods derived from [bioengineered] corn and 100 foods derived from [bioengineered] soybean." *Id.* Scientists "were able to detect rDNA in 13% of the soy products and 8% of the maize products." *Id.*

USDA explained that particularly when "refining food ingredients from agricultural inputs" to create "ingredients with a high degree of purity," such as "sugars and oils," it is "not surprising" that the "industrial processes" used "effectively eliminate the majority of undesired substances, including DNA and protein." 83 Fed. Reg. at 65,833-65,834 (2-SER-37-38). Noting that "[s]everal published studies have demonstrated that genetic material is not detectable in refined beet sugar or refined

cane sugar," USDA further explained that "[t]he sugar refining process from sugar beet or sugarcane juice that has been extracted by pressing or diffusion, then clarified and evaporated, results in sucrose of 99.9% purity." *Id.* at 65,834 (2-SER-38). "Several of these refining steps involve heating which serves to degrade DNA," and "prior to crystallization," chemical processes "remove" any "impurities remaining in the sugar juice." *Id.* Similarly, some processes used to create vegetable oils appear to degrade and remove any DNA from the plants that produced those oils. *Id.* "Based on the available scientific evidence, several countries (*e.g.* Australia, Brazil, Japan, Israel, New Zealand and South Korea) have exempted refined sugar," as well as refined vegetable oils, "from their respective [bioengineered] food labeling requirements." *Id.*

USDA noted that "based on the available scientific evidence, refined beet and cane sugar, high fructose corn syrup, degummed refined vegetable oils and various other refined ingredients are unlikely to require [bioengineered] food disclosure" because "the conditions of processing serve effectively to degrade or eliminate the DNA that was initially present in the raw agricultural commodity." 83 Fed. Reg. at 65,834 (2-SER-38). But the agency declined to "establish and maintain a list of ingredients excluded from the scope of the disclosure requirement." *Id.* at 65,839, 65,843 (2-SER-43; 2-SER-47). Instead, regulated entities that produce these sorts of products can avoid disclosure by maintaining records demonstrating the absence of modified genetic material under the same standards as those applicable to other products. *Id.* at 65,839, 65,843 (2-SER-43; 2-SER-47).

2. Plaintiffs' brief seeks to convert their disagreement with the agency's factual and policy judgments into asserted departures from the statute's commands. But contrary to plaintiffs' contention, the statute does not require labeling of any food that was made by using a bioengineered, raw agricultural commodity. As USDA explained, the statute defines the term "bioengineered" as referring to foods that "*contain*" certain modified genetic material. 83 Fed. Reg. at 65,816 (2-SER-20) (emphasis added) (quoting 7 U.S.C. § 1639(1)). Thus, "[f]oods with no modified genetic material are not bioengineered food." *Id.* at 65,836 (2-SER-40); *see id.* at 65,833, 65,834, 65,835, 65,839, 65,844, 65,845, 65,859, 65, 864, 65,868 (2-SER-37; 2-SER-38; 2-SER-39; 2-SER-43; 2-SER-48; 2-SER-49; 2-SER-63; 2-SER-68; 2-SER-72) (similar).

Plaintiffs stress (Br. 29-30) that the statute charges USDA with establishing "a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered," 7 U.S.C. § 1639b(a)(1). USDA indeed promulgated a standard that governs foods that may contain modified genetic material. And that standard puts the onus on regulated entities to "substantiate" claims that "products do not contain modified genetic material." 83 Fed. Reg. at 65,834; *see id.* at 65,843, 65,859 (2-SER-47; 2-SER-63); *see also id.* at 65,826-65,827, 65,852 (2-SER-30-31; 2-SER-56) (further explaining that foods on the List of Bioengineered Foods are presumptively bioengineered absent evidence to the contrary). Thus, if a food or ingredient is known to be bioengineered or made from a source that is known to be bioengineered, the food must be labeled as bioengineered unless the

regulated entity establishes otherwise. *See, e.g.*, *id.* at 65,826 (2-SER-30). As the district court explained, an array of foods are presumed to contain modified genetic material and "may escape the disclosure requirement only if the regulated entity provides records demonstrating that it is not bioengineered." 1-ER-22.

Plaintiffs are quite wrong to insist that the statute requires labeling any food that was made by using a bioengineered, raw agricultural commodity even when scientifically-validated testing establishes that the food does not contain modified genetic material. After all, the statute "appl[ies] to any claim in a disclosure that a food bears that indicates that the food *is* a bioengineered food." 7 U.S.C. § 1639a(a) (emphasis added). And the statute expressly sets out the "[r]equirements" for the labeling regulation, *id.* § 1639b(b)(2), which include that USDA should "determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food," *id.* § 1639b(b)(2)(B). Those requirements do not include that USDA must require labeling even when scientifically-validated means establish that foods do not contain modified genetic material.

Plaintiffs are thus also mistaken to suggest (Br. 26-29, 35-37) that USDA improperly engrafted a "detectability" requirement onto the statute. In promulgating the Final Rule, USDA reasonably chose to address the question of how to determine whether a food contains certain modified genetic material and therefore is bioengineered within the meaning of the statute. *See* 7 U.S.C. § 1639(1) (defining "[t]he term 'bioengineering', and any similar term, as determined by the Secretary" as

"refer[ing] to a food . . . that contains" certain modified "genetic material"). As discussed, USDA put the onus on regulated entities to "substantiate" any claims that "products do not contain modified genetic material." 83 Fed. Reg. at 65,834 (2-SER-38); *see id.* at 65,843, 65,859 (2-SER-47; 2-SER-63). And, as also discussed, USDA provided that they can do so in three logical and scientifically-validated ways, including that testing cannot detect any modified genetic material. *Id.* at 65,839, 65,843 (2-SER-43; 2-SER-47). Plaintiffs' contrary view would make the statutory inquiry turn not on whether the final food contains modified genetic material but whether a bioengineered product was used in its creation. That is not the inquiry required by the statute.

Plaintiffs' attempted reliance on legislative history (Br. 30-31, 38-41) only underscores the error of their position. Congress considered and rejected contentions advanced by plaintiffs here when it struck a "careful balance" on a number of key issues following "a hard-fought, tough negotiated agreement." 162 Cong. Rec. S4781 (daily ed. July 6, 2016) (statements of Sen. Roberts and Sen. Stabenow). In particular, some Members of Congress complained that because the statutory definition of "bioengineering" turned on whether a food "contains" certain modified genetic material, the statute would exclude foods that some people think should be covered and that some now-preempted laws do cover. Thus, Senator Leahy criticized what he viewed as the "very narrow scope of the definition" and said that it "would exclude a wide variety of highly processed foods, from soybean oil to corn oil, corn syrup to sugar

beets, and an array of other products that do not possess the actual genetic material after they have been processed." 162 Cong. Rec. S4845 (daily ed. July 7, 2016); *see id.* (adding that "even with the assurances from USDA last week, a simple study of this definition says that those foods that are highly processed and no longer have the modified genetic materials would not fall under this new label."). Senator Tester commented that the definition would exclude "a handful of products that are so refined" such that the "final product" would not be labeled "even when the original plant is GMO—soybean oil, high-fructose corn syrup, to give an example." 162 Cong. Rec. S4787 (daily ed. July 6, 2016). Senator Merkley noted what he viewed as a "loophole" in that the statutory definitions would not reach certain "products" such as "high-fructose corn syrup," "soybean oil" and "sugar" that are produced from genetically modified corn, soy, or sugarbeets. 162 Cong. Rec. S4802 (daily ed. July 6, 2016). He focused on the word "contains" in the statutory definition and said that in these products, the modified genetic material is "stripped out." *Id.*; *see id.* at S4804 (citing U.S. Food and Drug Administration (FDA) technical assistance as stating that these foods "wouldn't be covered"). Senator Boxer similarly objected that under "the definition," which she viewed as "narrow," "most of the products that really are engineered will not have to have the label." 162 Cong. Rec. S4789 (daily ed. July 6, 2016). Citing FDA technical assistance, she said that "many common foods made with genetically engineered corn syrup, sugar, and soybean oil would not be labeled under this bill[] . . . even though they are derived from genetically modified organisms." *Id.*

Indeed, many of the plaintiffs in this case expressed those views during the legislative process. In a letter to Congress, six of the eight organizations that are plaintiffs here criticized the law as "a non-labeling bill" that "exempts major portions of current and future GMO foods from labeling." 162 Cong. Rec. H4835 (daily ed. July 13, 2016) (quoted in statement of Rep. McGovern). They argued, among other things, that the "definition of 'bioengineering' . . . would exclude from labeling a vast number of current foods produced with genetic engineering," including those where "technology cannot as yet detect" any modified genetic material. *Id.* Those same plaintiffs now ask this Court to adopt the opposite interpretation of the same text.

Plaintiffs correctly note that several Members of Congress and USDA itself understood that the agency would have the "authority" to address highly refined products. *See* Br. 30-31. USDA did not suggest otherwise in promulgating the rule. The agency sought comment on how to regulate highly refined products and established that products made from bioengineered sources must ordinarily be labeled as bioengineered unless one of the scientifically-validated means set forth in the regulations establishes that the final food product does not contain modified genetic material. Nothing in the floor statements that plaintiffs cite suggest that, as matter of law, a food that contains no detectable modified genetic material must irrebuttably be presumed to be bioengineered.

3. Plaintiffs reframe many of the same arguments as contentions that USDA acted arbitrarily and capriciously in its evaluation of the available data or should have

reached a different balance between competing preferences and policy considerations. These arguments, to a significant extent, simply take issue with judgments reached in the passage of highly contested legislation. These arguments also fail to apprehend the applicable principles of administrative law. A court "is not to substitute its judgment for that of the agency" but instead reviews the agency decision to determine whether it "may reasonably be discerned" that the agency "examine[d] the relevant" information and identified "a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quotation marks omitted); *see Solar Energy Indus. Ass'n v. Federal Energy Regulatory Comm'n*, 80 F.4th 956, 978 (9th Cir. 2023).

Plaintiffs' arguments largely reduce to the contention that scientifically-validated means of determining whether a food contains modified genetic material cannot be trusted and that USDA acted unreasonably by concluding otherwise. Thus, in plaintiffs' view, any food produced by using some bioengineered, raw agricultural source must be deemed bioengineered even in the face of validated evidence to the contrary. That is not the conclusion reflected in the legislation, and the only material in the administrative record (or otherwise) that plaintiffs point to are studies (and guidance) suggesting that DNA testing has become increasingly sensitive over the years. *See* Br. 43-44. The fact that testing can now detect even minuscule traces of genetic material underscores that USDA reasonably chose to allow regulated entities to use validated testing to establish that their foods do not contain certain genetic material.

As USDA explained, moreover, if scientific testing should become even more sensitive in the future, it would generally be incumbent on regulated entities to make use of those tests when testing for the presence of modified genetic material or validating a refining process. *See* 7 C.F.R. § 66.9. In addition, if as a result of improved testing, or for any other reason, a regulated entity comes to know that a food is bioengineered, then the food must be labeled. *Id.* § 66.109. USDA recognized that "emerging technologies" could affect what foods require disclosure and that "testing methodology may evolve so that a future test may detect genetic material in a food ingredient that current tests do not." 83 Fed. Reg. at 65,834 (2-SER-38). But the theoretical possibility that future testing methods might be able to detect even more minute traces of genetic material does not suggest that USDA's decision to rely on testing at all was arbitrary and capricious. As the district court explained, the alternative would be "to require results impossible to obtain with existing technology." 1-ER-23. Plaintiffs observe that "[a] house may contain mold, whether or not it is detected by the eyes of the homeowner." Br. 43. But if a sophisticated home inspection using validated testing finds no mold, it is reasonable to accept that the house does not contain mold.

Plaintiffs also restate their contention that "undoubtedly, highly refined foods 'contain' genetic material that 'has been modified.'" Br. 28; *see* Br. 42-46. USDA discussed contrary evidence at length. *See, e.g.*, 83 Fed. Reg. at 65,833-65,834 (2-SER-37-38). But more to the point, the Final Rule does not exempt highly refined foods, and USDA ultimately declined to "establish and maintain a list of ingredients

excluded from the scope of the disclosure requirement." *Id.* at 65,839, 65,843 (2-SER-43; 2-SER-47). The Final Rule simply provides three logical and scientifically-validated ways that a regulated entity can establish that a food—highly refined or otherwise—does not contain modified genetic material and therefore is not bioengineered under this statute.

B. USDA Reasonably Required Disclosures Of "Bioengineered" Foods To Use The Word "Bioengineered"

The district court also properly rejected plaintiffs' objections to the required disclosure terminology. *See* 1-ER-21-22. The Final Rule requires that disclosures use the word "bioengineered." 7 C.F.R. §§ 66.102, 66.104(a), 66.106(b)(2), 66.108(a), (b). Regulated entities can choose to provide additional information regarding bioengineered foods and can make additional statements or use additional terms beyond "bioengineered." *See id.* § 66.118; 83 Fed. Reg. at 65,852 (2-SER-56); *see also id.* at 65,858-65,859 (2-SER-62-63). Plaintiffs appear to contend, however, that USDA was required to choose a different term, such as "genetically engineered," "genetically modified," "GE," or "GMO," or to offer regulated entities a menu of different terms that they could use instead of "bioengineered."

1. USDA had ample basis to require that the bioengineered food disclosure use the term "bioengineered." The statute uses the term "bioengineered" throughout and gives "[t]he term 'bioengineering', and any similar term, as determined by the Secretary," a very specific meaning. 7 U.S.C. § 1639(1). It refers to "a food—(A) that contains

genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and (B) for which the modification could not otherwise be obtained through conventional breeding or found in nature." *Id.* The definition does not encompass other methods of modifying DNA or modifications that can be achieved through conventional breeding or found in nature. *See id.* The terms "bioengineering and bioengineered food accurately reflect[] the scope of disclosure and the products and potential technology at issue." 83 Fed. Reg. at 65,837 (2-SER-41); *see id.* at 65,851-65,852 (2-SER-55-56).

USDA "considered similar terms to bioengineering as permitted by the amended Act," 83 Fed. Reg. at 65,837 (2-SER-41), and had ample basis for declining to use such other terms. Using other terms, such as "genetic engineering" or "genetically modified organism," which have varied meanings in colloquial use and in other state and federal regimes, could "muddy the scope of disclosure." *Id.* Among other things, such terms "encompass[] a broad range of methods that can be used to alter the genetic composition of a plant," not just recombinant DNA techniques. 3-SER-121-122; 3-SER-125 (FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants* (2015)); *see also* 162 Cong. Rec. S4787 (daily ed. July 6, 2016) (statement of Sen. Tester) (explaining that the statutory definition of "bioengineering" does not encompass the "only way[s] we modify plants and animals," such as "cell fusion, macroinjection, gene deletion, gene editing" and future technologies). Indeed, six of the eight plaintiffs here urged Members of Congress

to vote against this law because it utilized a "novel definition of 'bioengineering'" that would not cover foods "where the 'modification' is 'found in nature'" or "made with non in vitro recombinant DNA techniques, such as new generations of food made with RNAi and so-called 'gene-editing' techniques." 162 Cong. Rec. H4835 (daily ed. July 13, 2016) (quoted in statement of Rep. McGovern).

USDA also explained that using other terms may "create inconsistencies" with the statute's "preemption provisions." 83 Fed. Reg. at 65,837 (2-SER-41). The statute draws a distinction between the terms "bioengineering" and "genetic engineering" in a provision that prohibits States and local governments from regulating the labeling of any food that "is genetically engineered" or "was developed or produced using genetic engineering." 7 U.S.C. § 1639i(b). The Senate Report explained that "Congress selected the term 'genetically engineered'" in that one section of the statute "to broadly preempt state, tribal, and local requirements regarding genetically engineered foods or seed regardless of whether the technology used to develop the food or seed falls within the definition of bioengineering." Senate Report 6.

2. Plaintiffs stress that the statute defines "[t]he term 'bioengineering', and any similar term, as determined by the Secretary" as referring to food that contains certain kinds of modified genetic material, 7 U.S.C. § 1639(1), from which plaintiffs seek to infer that the statute requires "USDA to use similar terms." Br. 52-53. The district court correctly recognized that nothing in the statute "indicates that Congress intended to require that 'any similar term' be part of the mandatory disclosure language."

1-ER-21. Plaintiffs also argue for the first time that because the statute "allows USDA" to use "any similar term, as determined by the Secretary," it is therefore impossible that any similar term could be confusing. *See* Br. 52-53 (quotation marks omitted). No sound basis exists for that conclusion, and the statute left it to the agency to select appropriate disclosure terms.

Plaintiffs do not advance their argument by noting that in other contexts, such as when implementing a different statute, USDA and FDA have used terms like "GE," "genetic engineering" and "GMO" (Br. 53-54, 56); that some Members of Congress used such terms in legislative debates (Br. 51); that USDA initially considered using the term "GMO" for this rule (Br. 54); and that people outside of the federal government use "GE" and "GMO" in various contexts (Br. 54-55). As discussed, the governing statute uses the term "bioengineering" and established a specific definition that is distinct from how many people use these other terms. It may be that USDA could reasonably have chosen a different term or terms for the bioengineered food disclosure. But USDA chose the term "bioengineered," and, in so doing, "acted within a zone of reasonableness," "reasonably considered the relevant issues," and "reasonably explained the decision." *Federal Commc'ns Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). Contrary to plaintiffs' suggestion, that decision was not an unexplained "about-face." Br. 54. The agency fully explained its decision, and, as the district court observed, "the use of the term bioengineered cannot be characterized as

a change in practice or policy because the disclosure statute and regulations are the first federal actions implementing standards for bioengineered food disclosures." 1-ER-21.

Plaintiffs fare no better when they note (Br. 55) one study by Campbell Soup Company suggesting that consumers are not familiar with the term "bioengineered." USDA acknowledged that some commenters urged USDA to use "a familiar term." 83 Fed. Reg. at 65,851 (2-SER-55). But USDA chose to use the statutory term "bioengineered," rather than a term that may be more familiar but also connotes a different meaning, to "ensur[e] disclosure consistency" and "minimize[e] market-place confusion." *Id.* USDA also stated that it would "engage in outreach and education to provide information about the new disclosure term." *Id.* at 65,851, 65,852 (2-SER-55; 2-SER-56); *see also id.* at 65,853 (2-SER-57) (explaining that as the new rule is implemented, USDA "is committed to helping consumers understand the meaning of the new symbol and accompanying text").

II. The District Court Did Not Abuse Its Discretion In Remanding The Text-Message Disclosure Option Without Vacatur

Plaintiffs also contend (Br. 57-60) that the district court abused its discretion when, after holding USDA erred by creating a text-message disclosure option, the court then remanded the matter to the agency without vacatur. The district court had ample basis to exercise its discretion in that manner, and plaintiffs' contrary arguments misunderstand the district court's decision and its exercise of equitable discretion.

A. This Court has made clear that "[a] flawed rule need not be vacated." *California Cmtys. Against Toxics v. U.S. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (per curiam). Under this Court's cases, the decision whether to vacate a rule or to remand a rule for the agency to address errors without vacating that rule is an equitable one. *Id.*; *see, e.g.*, *Migrant Clinicians Network v. U.S. EPA*, 88 F.4th 830, 847-848 (9th Cir. 2023). As the district court recognized, that exercise of a court's discretion is guided by two factors: "the seriousness of the agency's errors" and "the disruptive consequences of an interim change that may itself be changed." *Migrant Clinician's Network*, 88 F.4th at 848.

The district court properly considered those factors and declined to vacate. Even assuming, as the district court concluded, that "[t]he text message disclosure decision was a significant error," the court was well within its discretion to find that two disruptive consequences of vacatur strongly counseled in favor of leaving the text-message option in place pending further proceedings. 1-ER-21.

Vacating the text-message option would "disrupt the food industry, which was required to comply with the regulations as of January 1, 2022." 1-ER-21; *see* 7 C.F.R. § 66.13 (establishing an "implementation date" of January 1, 2020, and requiring compliance with all requirements by January 1, 2022). Any regulated entity that uses only a text-message disclosure would be out of compliance. They could not bring themselves into compliance until they created new labels and, quite possibly, set up systems for electronic disclosure. And once USDA issued a revised regulation

following the district court's decision, those resources might turn out to be wasted and that work may have to be redone.

In consequence, vacatur would also "disrupt consumer access to bioengineering disclosures." 1-ER-21. Because any transition would take time, packages that contain a text-message disclosure could remain on shelves after the text-message systems have been shut down. The absence of the text-message option could also make it harder for at least some consumers to access information. Indeed, for food in "small and very small packages," it can be logistically difficult to have a text or symbol disclosure on the food label, and without the text-message option, manufacturers can limit themselves to a scannable link or a phone number. *See* 7 C.F.R. § 66.112. The district court concluded that the text-message option did not go far enough in providing additional disclosure to people who have difficulty accessing the electronic option. But vacating the text-message option would only compound the error. *See, e.g.*, *Center for Food Safety v. Regan*, 56 F.4th 648, 668 (9th Cir. 2022) (ordering remand without vacatur in part because the challenged rule maintained "enhanced protection" of the "values" at issue); *Natural Res. Def. Council v. U.S. EPA*, 38 F.4th 34, 59-60 (9th Cir. 2022) (declining to vacate requirements that are "insufficient" but may well "reduce" the targeted "risk"); *California Cmtys. Against Toxics*, 688 F.3d at 994 (similar).

B. 1. Plaintiffs' contentions that the district court failed to engage in the proper equitable balancing misread the court's decision. *See* Br. 58-60. The district court did not "fail[] to weigh the seriousness" of the agency's mistake. Br. 58. The court made

clear that "[w]hether remand without vacatur is appropriate 'depends on how serious the agency's errors are *and* the disruptive consequences of an interim change that may itself be changed.'" 1-ER-20 (emphasis added). The court then applied those considerations and, as plaintiffs acknowledge, began by stating that it viewed "[t]he text message disclosure decision" as "a significant error." 1-ER-21. That the district court did not ultimately vacate the rule, as plaintiffs urged, does not mean that the court disregarded this consideration.

Nor, contrary to plaintiffs' assertion, did the district court "defer to USDA's litigation position" about the disruptive consequences of vacatur. Br. 58 (emphasis omitted); *see* Br. 58-59 (arguing that "deference" was inappropriate). The court made clear that the government bears the burden, explaining that "vacatur is the typical remedy in these circumstances, *unless the government establishes* why another remedy, such as remand without vacatur, is a better result." 1-ER-20 (emphasis added). The court then agreed with the government's arguments that vacatur would "disrupt consumer access to bioengineering disclosures and exacerbate the very concerns implicated by the agency's error" and that "vacatur would disrupt the food industry, which was required to comply with the regulations as of January 1, 2022." 1-ER-21. The court found these concerns "legitimate and persuasive" and "[c]onsequently" remanded without vacatur. 1-ER-21. That the court agreed with the government's arguments does not mean that the court deferred to them.

2. Plaintiffs' passing suggestions that vacatur is unlikely to be disruptive fare no better. Plaintiffs premise that contention on a misunderstanding of the district court's decision when they describe the court's order as invalidating "standalone QR code disclosures" (Br. 57) or "QR code labeling" (Br. 59), and they suggest that vacatur would have entailed "vacatur of the QR code alternative" (Br. 59-60). The Final Rule allowed for four types of disclosure: a text disclosure, a symbol disclosure, an electronic or digital link disclosure that plaintiffs call a "QR code" but that also provides a phone number to call, and a text-message disclosure. 7 C.F.R. § 66.100(b); *see id.* § 66.102 (text disclosure); *id.* § 66.104 (symbol disclosure); *id.* § 66.106 (electronic or digital link disclosure with phone adjunct); *id.* § 66.108 (text-message disclosure). The district court considered plaintiffs' challenge to "USDA's decision to provide a text message disclosure option," 1-ER-16, and the court held that USDA's "decision to implement a standalone text message disclosure option was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,'" 1-ER-20 (quoting 5 U.S.C. § 706(2)(A)); *see* 1-ER-17-19. Thus, when considering whether to remand without vacatur, the court stated that "[t]he text message disclosure decision was a significant error" but that the disruptive consequences of vacating that option ultimately carried the day. 1-ER-20-21.

Plaintiffs' arguments about the disruptive consequences of vacatur seem to assume that once the district court invalidated the text-message option, it would have then "vacated" both the text-message option and the electronic disclosure option. But

invalidating the severable text-message option does not invalidate the separate electronic option. *See* 7 C.F.R. § 66.11 ("If any provision of this part is declared invalid . . . , the validity of the remainder of this part . . . shall not be affected thereby."). Plaintiffs therefore would have been—and apparently now are—seeking a further, and presumably temporary, injunction that would effectively bar regulated entities from using the electronic disclosure option until USDA devised a new "additional and comparable" option, 7 U.S.C. § 1639b(c)(4).

That remedy likely would have been improper given that the statute itself directs that regulated entities be allowed to choose a digital or electronic disclosure option, *see* 7 U.S.C. § 1639b(b)(2)(D), (d), and provides for the possibility of "additional and comparable options" without stating that the electronic options are otherwise invalid, *see id.* § 1639b(c)(4). But more to the point, plaintiffs never sought that remedy and instead just broadly urged the court to "vacate the Disclosure Standard." 1-ER-146-147. Thus, in response to the government's arguments that vacatur would disrupt the flow of information to consumers, plaintiffs said nothing about vacating the electronic disclosure option at all, even though they seem to view that remedy as facilitating the flow of information to consumers. *See* 1-ER-53. Plaintiffs instead just disputed whether manufacturers "would spend money to change their labels in the interim." 1-ER-53. The district court did not abuse its discretion by declining an equitable remedy the plaintiffs never sought.

In all events, plaintiffs' newfound proposal to "vacate"—really to universally enjoin—both the text-message and electronic disclosure options would also have been highly disruptive. That remedy would have been even more disruptive for regulated entities because any label bearing two of the four disclosure options—the electronic or text-message disclosures—would have been in violation. The most that plaintiffs can say is that "numerous manufacturers were already opting for on-package text and symbols." Br. 59. That has no bearing on the manufacturers, importers, and retailers who do not use those two options. And, indeed, any benefit to plaintiffs of the remedy they now seek depends on its disruptive consequences to manufacturers: if vacatur has no effect on industry, then it has no benefit to plaintiffs. That broader remedy, once implemented, may well have mitigated the harms to disclosure for some persons who have difficulty accessing the electronic disclosure. But particularly because the electronic disclosure option requires not only a link but also a phone number to call, 7 C.F.R. § 66.106(a)(2), it is unclear how significant that benefit would be. And for those consumers who can use the electronic or text-message options, shutting down those forms of disclosure may deprive those consumers of information while USDA is reconsidering the issue.

C. If this Court were to conclude that the district court abused its equitable discretion, the appropriate disposition would be to remand the case so that the district court can reweigh the equities in the first instance. Although this Court's precedents identify vacatur as an available remedy for a successful APA challenge to a regulation,

see, e.g., *California Wilderness Coal. v. U.S. Dep't of Energy*, 631 F.3d 1072, 1095 (9th Cir. 2011), the government's position is that the APA does not authorize vacatur and instead remits plaintiffs to traditional equitable remedies like injunctions, *see* 5 U.S.C. § 703; *see also United States v. Texas*, 599 U.S. 670, 693-703 (2023) (Gorsuch, J., concurring in the judgment) (detailing "serious" arguments that "warrant careful consideration" as to whether the APA "empowers courts to vacate agency action"). In any event, this Court has treated universal vacatur of agency action as a discretionary equitable remedy—not a remedy that is automatic or compelled. *See supra* pp. 39, 40. And, as discussed, the remedy that plaintiffs now seek—an order that would permanently bar the text-message option and temporarily bar the electronic disclosure option—is not a vacatur under any conception of that term.

Thus, under any view, a weighing of the equities would be necessary. Particularly if plaintiffs' requested remedy were properly understood as an injunction, the district court would, in the first instance, have to make determinations about how the specific disclosure options harm the plaintiffs and then limit any equitable remedy to addressing their injury. Under Article III, court orders should be "limited" and "tailored" to redress the parties' "particular injury." *Gill v. Whitford*, 585 U.S. 48, 68, 73 (2018). And equitable orders must "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979); *see Trump v. Hawaii*, 585 U.S. 667, 716-718 (2018) (Thomas, J., concurring). Indeed, even if a court wishes to issue an order styled as a "vacatur," that order should be

tailored to the parties before the court, in accordance with traditional equitable principles. *Texas*, 599 U.S. at 702-704 (Gorsuch, J., concurring in the judgment). The district court would also presumably consider the various harms to consumers and regulated entities that would flow from plaintiffs' proposed remedy. The district court may also have to take account of the way that Congress structured the disclosure regime in the governing statute. *See United States v. Oakland Cannabis Buyers' Coop.*, 532 U.S. 483, 497 (2001) ("[A] court sitting in equity cannot ignore the judgment of Congress, deliberately expressed in legislation" (quotation marks omitted)).

CONCLUSION

For the foregoing reasons, the judgment of the district court should be affirmed.

Respectfully submitted,

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STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, the government is unaware of any related case pending in this Court.

s/ Adam Jed
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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 11,602 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

s/ Adam Jed
ADAM C. JED

STATUTORY AND REGULATORY ADDENDUM

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STATUTES

7 U.S.C. § 1639

(1) Bioengineering

The term "bioengineering", and any similar term, as determined by the Secretary, with respect to a food, refers to a food--

(A) that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques; and

(B) for which the modification could not otherwise be obtained through conventional breeding or found in nature.

(2) Food

The term "food" means a food (as defined in section 321 of Title 21) that is intended for human consumption.

(3) Secretary

The term "Secretary" means the Secretary of Agriculture.

7 U.S.C. § 1639a

(a) In general

This subchapter shall apply to any claim in a disclosure that a food bears that indicates that the food is a bioengineered food.

(b) Application of definition

The definition of the term "bioengineering" under section 1639 of this title shall not affect any other definition, program, rule, or regulation of the Federal Government.

(c) Application to foods

This subchapter shall apply only to a food subject to--

(1) the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(2) the labeling requirements under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.) only if--

(A) the most predominant ingredient of the food would independently be subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); or

(B)(i) the most predominant ingredient of the food is broth, stock, water, or a similar solution; and

(ii) the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

7 U.S.C. § 1639b

(a) Establishment of mandatory standard

Not later than 2 years after July 29, 2016, the Secretary shall--

(1) establish a national mandatory bioengineered food disclosure standard with respect to any bioengineered food and any food that may be bioengineered; and

(2) establish such requirements and procedures as the Secretary determines necessary to carry out the standard.

(b) Regulations

(1) In general

A food may bear a disclosure that the food is bioengineered only in accordance with regulations promulgated by the Secretary in accordance with this subchapter.

(2) Requirements

A regulation promulgated by the Secretary in carrying out this subchapter shall--

(A) prohibit a food derived from an animal to be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance;

(B) determine the amounts of a bioengineered substance that may be present in food, as appropriate, in order for the food to be a bioengineered food;

(C) establish a process for requesting and granting a determination by the Secretary regarding other factors and conditions under which a food is considered a bioengineered food;

(D) in accordance with subsection (d), require that the form of a food disclosure under this section be a text, symbol, or electronic or digital link, but excluding Internet website Uniform Resource Locators not embedded in the link, with the disclosure option to be selected by the food manufacturer;

(E) provide alternative reasonable disclosure options for food contained in small or very small packages;

(F) in the case of small food manufacturers, provide--

(i) an implementation date that is not earlier than 1 year after the implementation date for regulations promulgated in accordance with this section; and

(ii) on-package disclosure options, in addition to those available under subparagraph (D), to be selected by the small food manufacturer, that consist of--

(I) a telephone number accompanied by appropriate language to indicate that the phone number provides access to additional information; and

(II) an Internet website maintained by the small food manufacturer in a manner consistent with subsection (d), as appropriate; and

(G) exclude--

(i) food served in a restaurant or similar retail food establishment; and

(ii) very small food manufacturers.

(3) Safety

For the purpose of regulations promulgated and food disclosures made pursuant to paragraph (2), a bioengineered food that has successfully completed the pre-market Federal regulatory review process shall not be treated as safer than, or not as safe as, a non-bioengineered counterpart of the food solely because the food is bioengineered or produced or developed with the use of bioengineering.

(c) Study of electronic or digital link disclosure

(1) In general

Not later than 1 year after July 29, 2016, the Secretary shall conduct a study to identify potential technological challenges that may impact whether consumers would have access to the bioengineering disclosure through electronic or digital disclosure methods.

(2) Public comments

In conducting the study under paragraph (1), the Secretary shall solicit and consider comments from the public.

(3) Factors

The study conducted under paragraph (1) shall consider whether consumer access to the bioengineering disclosure through electronic or digital disclosure methods under this subchapter would be affected by the following factors:

(A) The availability of wireless Internet or cellular networks.

(B) The availability of landline telephones in stores.

(C) Challenges facing small retailers and rural retailers.

(D) The efforts that retailers and other entities have taken to address potential technology and infrastructure challenges.

(E) The costs and benefits of installing in retail stores electronic or digital link scanners or other evolving technology that provide bioengineering disclosure information.

(4) Additional disclosure options

If the Secretary determines in the study conducted under paragraph (1) that consumers, while shopping, would not have sufficient access to the bioengineering disclosure through electronic or digital disclosure methods, the Secretary, after consultation with food retailers and manufacturers, shall provide additional and comparable options to access the bioengineering disclosure.

(d) Disclosure

In promulgating regulations under this section, the Secretary shall ensure that--

(1) on-package language accompanies--

(A) the electronic or digital link disclosure, indicating that the electronic or digital link will provide access to an Internet website or other landing page by stating only "Scan here for more food information", or equivalent language that only reflects technological changes; or

(B) any telephone number disclosure, indicating that the telephone number will provide access to additional information by stating only "Call for more food information.";

(2) the electronic or digital link will provide access to the bioengineering disclosure located, in a consistent and conspicuous manner, on the first product information page that appears for the product on a mobile device, Internet website, or other landing page, which shall exclude marketing and promotional information;

(3)(A) the electronic or digital link disclosure may not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers; but

(B) if information described in subparagraph (A) must be collected to carry out the purposes of this subchapter, that information shall be deleted immediately and not used for any other purpose;

(4) the electronic or digital link disclosure also includes a telephone number that provides access to the bioengineering disclosure; and

(5) the electronic or digital link disclosure is of sufficient size to be easily and effectively scanned or read by a digital device.

(e) State food labeling standards

Notwithstanding section 1639i of this title, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for a food that is the subject of the national bioengineered food disclosure standard under this section that is not identical to the mandatory disclosure requirement under that standard.

(f) Consistency with certain laws

The Secretary shall consider establishing consistency between--

(1) the national bioengineered food disclosure standard established under this section; and

(2) the Organic Foods Production Act of 1990 (7 U.S.C. 6501 et seq.) and any rules or regulations implementing that Act.

(g) Enforcement

(1) Prohibited act

It shall be a prohibited act for a person to knowingly fail to make a disclosure as required under this section.

(2) Recordkeeping

Each person subject to the mandatory disclosure requirement under this section shall maintain, and make available to the Secretary, on request, such records as the Secretary determines to be customary or reasonable in the food industry, by regulation, to establish compliance with this section.

(3) Examination and audit

(A) In general

The Secretary may conduct an examination, audit, or similar activity with respect to any records required under paragraph (2).

(B) Notice and hearing

A person subject to an examination, audit, or similar activity under subparagraph (A) shall be provided notice and opportunity for a hearing on the results of any examination, audit, or similar activity.

(C) Audit results

After the notice and opportunity for a hearing under subparagraph (B), the Secretary shall make public the summary of any examination, audit, or similar activity under subparagraph (A).

(4) Recall authority

The Secretary shall have no authority to recall any food subject to this subchapter on the basis of whether the food bears a disclosure that the food is bioengineered.

7 U.S.C. § 1639i

(a) Definition of food

In this subchapter, the term "food" has the meaning given the term in section 321 of Title 21.

(b) Federal preemption

No State or a political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food or seed in interstate commerce any

requirement relating to the labeling of whether a food (including food served in a restaurant or similar establishment) or seed is genetically engineered (which shall include such other similar terms as determined by the Secretary of Agriculture) or was developed or produced using genetic engineering, including any requirement for claims that a food or seed is or contains an ingredient that was developed or produced using genetic engineering.

REGULATIONS

7 C.F.R. § 66.1

Act means the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.), as amended to include Subtitle E—National Bioengineered Food Disclosure Standard and Subtitle F—Labeling of Certain Food.

Administrator means the Administrator of the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

AMS means the Agricultural Marketing Service of the United States Department of Agriculture.

Bioengineered food means—

(1) Subject to the factors, conditions, and limitations in paragraph (2) of this definition:

(i) A food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature; provided that

(ii) Such a food does not contain modified genetic material if the genetic material is not detectable pursuant to § 66.9.

(2) A food that meets one of the following factors and conditions is not a bioengineered food.

(i) An incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in 21 CFR 101.100(a)(3).

(ii) [Reserved]

Bioengineered substance means substance that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

Compliance date means—

(1) Mandatory compliance date. Entities responsible for bioengineered food disclosure must comply with the requirements of this part by January 1, 2022.

(2) Updates to the List of Bioengineered Foods. When AMS updates the List of Bioengineered Foods pursuant to § 66.7, entities responsible for bioengineered food disclosures must comply with the updates no later than 18 months after the effective date of the update.

Food means a food (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) that is intended for human consumption.

Food manufacturer means an entity that manufactures, processes, or packs human food and labels the food or food product for U.S. retail sale.

Importer means the importer of record, as determined by U.S. Customs and Border Protection (19 U.S.C. 1484(a)(2)(B)), who engages in the importation of food or food products labeled for retail sale into the United States.

Information panel means that part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes (e.g. irregular shape with one usable surface).

Label means a display of written, printed, or graphic matter upon the immediate container or outside wrapper of any retail package or article that is easily legible on or through the outside container or wrapper.

Labeling means all labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers; or

(2) Accompanying such article.

List of Bioengineered Foods means a list, maintained and updated by AMS and provided in § 66.6, of foods for which bioengineered versions have been developed.

Marketing and promotional information means any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs that are distributed, broadcast, or made available to assist in the sale or promotion of a product.

Predominance means an ingredient's position in the ingredient list on a product's label. Predominant ingredients are those most abundant by weight in the product, as required under 21 CFR 101.4(a)(1).

Principal display panel means that part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

Processed food means any food other than a raw agricultural commodity, and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

Raw agricultural commodity means any agricultural commodity in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

Regulated entity means the food manufacturer, importer, or retailer that is responsible for making bioengineered food disclosures under § 66.100(a).

Secretary means the United States Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

Similar retail food establishment means a cafeteria, lunch room, food stand, food truck, transportation carrier (such as a train or airplane), saloon, tavern, bar, lounge, other similar establishment operated as an enterprise engaged in the business of selling prepared food to the public, or salad bars, delicatessens, and other food

enterprises located within retail establishments that provide ready-to-eat foods that are consumed either on or outside of the retailer's premises.

Small food manufacturer means any food manufacturer with annual receipts of at least $2,500,000, but less than $10,000,000.

Small package means food packages that have a total surface area of less than 40 square inches.

Very small food manufacturer means any food manufacturer with annual receipts of less than $2,500,000.

Very small package means food packages that have a total surface area of less than 12 square inches.

7 C.F.R. § 66.3

(a) General.

(1) A label for a bioengineered food must bear a disclosure indicating that the food is a bioengineered food or contains a bioengineered food ingredient consistent with this part.

(2) Except as provided in § 66.116 for voluntary disclosure, a label shall not bear a disclosure that a food is a bioengineered food or contains a bioengineered food ingredient if the records maintained in accordance with § 66.302 demonstrate that the food is not a bioengineered food or does not contain a bioengineered food ingredient.

(b) Application to food. This part applies only to a food subject to:

(1) The labeling requirements under the Federal Food, Drug, and Cosmetic Act ("FDCA"); or

(2) The labeling requirements under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act only if:

(i) The most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA; or

(ii) The most predominant ingredient of the food is broth, stock, water, or a similar solution and the second-most predominant ingredient of the food would independently be subject to the labeling requirements under the FDCA.

7 C.F.R. § 66.5

This part shall not apply to the food and entities described in this section.

(a) Food served in a restaurant or similar retail food establishment.

(b) Very small food manufacturers.

(c) A food in which no ingredient intentionally contains a bioengineered (BE) substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient.

(d) A food derived from an animal shall not be considered a bioengineered food solely because the animal consumed feed produced from, containing, or consisting of a bioengineered substance.

(e) Food certified under the National Organic Program.

7 C.F.R. § 66.6

The List of Bioengineered Foods consists of the following: Alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer, coat protein-mediated virus-resistant varieties), sugarbeet, and sugarcane (Bt insect-resistant varieties).

7 C.F.R. § 66.7

(a) Updates to the List. AMS will review and consider updates to the List on an annual basis and will solicit recommendations regarding updates to the List through notification in the Federal Register and on the AMS website.

(1) Recommendations regarding additions to and subtractions from the List may be submitted to AMS at any time or as part of the annual review process.

(2) Recommendations should be accompanied by data and other information to support the recommended action.

(3) AMS will post public recommendations on its website, along with information about other revisions to the List that the agency may be considering, including input based on consultation with the government agencies responsible for oversight of the products of biotechnology: USDA's Animal and Plant Health Inspection Service (USDA–APHIS), the U.S. Environmental Protection Agency (EPA), and the Department of Health and Human Services' Food and Drug Administration (FDA), and appropriate members of the Coordinated Framework for the Regulation of Biotechnology or a similar successor.

(4) AMS will consider whether foods proposed for inclusion on the List have been authorized for commercial production somewhere in the world, and whether the food is currently in legal commercial production for human food somewhere in the world.

(5) If AMS determines that an update to the List is appropriate following its review of all relevant information provided, AMS will modify the List.

(b) Compliance period. Regulated entities will have 18 months following the effective date of the updated List of Bioengineered Foods to revise food labels to reflect changes to the List in accordance with the disclosure requirements of this part.

7 C.F.R. § 66.9

(a) Recordkeeping requirements. Modified genetic material is not detectable if, pursuant to the recordkeeping requirements of § 66.302, the entity responsible for making a BE food disclosure maintains:

(1) Records to verify that the food is sourced from a non-bioengineered crop or source; or

(2) Records to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; or

(3) Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material.

(b) Validated refining process.

(1) Analytical testing that meets the standards described in paragraph (c) of this section must be used to validate that a refining process renders modified genetic material in a food undetectable.

(2) Once a refining process has been so validated, additional testing is not necessary to confirm the absence of detectable modified genetic material in food subsequently refined through that process, provided that no significant changes are made to the validated process and provided that records are maintained to demonstrate that the refining process has been validated and that the validated refining process is followed.

(c) Standards of performance for detectability testing. Analytical testing for purposes of detecting the presence of modified genetic material in refined foods pursuant to paragraph (a) of this section shall meet the following standard:

(1) Laboratory quality assurance must ensure the validity and reliability of test results;

(2) Analytical method selection, validation, and verification must ensure that the testing method used is appropriate (fit for purpose) and that the laboratory can successfully perform the testing;

(3) The demonstration of testing validity must ensure consistent accurate analytical performance; and

(4) Method performance specifications must ensure analytical tests are sufficiently sensitive for the purposes of the detectability requirements of this part.

7 C.F.R. § 66.100

(a) Responsibility for disclosure.

(1) For a food that is packaged prior to receipt by a retailer, the food manufacturer or importer is responsible for ensuring that the food label bears a bioengineered food disclosure in accordance with this part.

(2) If a retailer packages a food or sells a food in bulk, that retailer is responsible for ensuring that the food bears a bioengineered food disclosure in accordance with this part.

(b) Type of disclosure. If a food must bear a bioengineered food disclosure under this part, the disclosure must be in one of the forms described in this paragraph (b), except as provided in §§ 66.110 and 66.112.

(1) A text disclosure in accordance with § 66.102.

(2) A symbol disclosure in accordance with § 66.104.

(3) An electronic or digital link disclosure in accordance with § 66.106.

(4) A text message disclosure in accordance with § 66.108.

(c) Appearance of disclosure. The required disclosure must be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

(d) Placement of the disclosure. Except as provided in § 66.114 for bulk food, the disclosure must be placed on the label in one of the manners described in this paragraph (d).

(1) The disclosure is placed in the information panel directly adjacent to the statement identifying the name and location of the handler, distributor, packer, manufacturer, importer, or any statement disclosing similar information.

(2) The disclosure is placed in the principal display panel.

(3) The disclosure is placed in an alternate panel likely to be seen by a consumer under ordinary shopping conditions if there is insufficient space to place the disclosure on the information panel or the principal display panel.

(e) Uniform Resource Locator (URL). Except for disclosures made by small manufacturers and for disclosures on very small packages, a bioengineered food disclosure may not include an internet website URL that is not embedded in an electronic or digital link.

7 C.F.R. § 66.102

A text disclosure must bear the text as described in this section. A text disclosure may use a plural form if applicable, e.g. if a food product includes more than one bioengineered food, then "bioengineered foods" or "bioengineered food ingredients" may be used.

(a) Bioengineered foods. If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is bioengineered, the text disclosure must be one of the following, as applicable:

(1) "Bioengineered food" for bioengineered food that is a raw agricultural commodity or processed food that contains only bioengineered food ingredients; or

(2) "Contains a bioengineered food ingredient" for multi-ingredient food that is not described in paragraph (a)(1) of this section but contains one or more bioengineered food ingredients.

(b) Predominant language in U.S. Food subject to disclosure that is distributed solely in a U.S. territory may be labeled with statements equivalent to those required in this part, using the predominant language used in that territory.

7 C.F.R. § 66.104

A symbol disclosure must replicate the form and design of Figure 1 to this section.

(a) The symbol is a circle with a green circumference, and a white outer band. The bottom portion of the circle contains an arch, filled in green to the bottom of the circle. The arch contains two light green terrace lines, sloping downward from left to right. On the left side of the arch is a stem arching towards the center of the circle, ending in a four-pointed starburst. The stem contains two leaves originating on the upper side of the stem and pointing towards the top of the circle. In the background of the leaves, at the top of the circle and to the left of center, is approximately one-half of a circle filled in yellow. The remainder of the circle is filled in light blue. The symbol must contain the words "BIOENGINEERED."

(b) If a food (including any ingredient produced from such food) is on the List of Bioengineered Foods, and records maintained by a regulated entity demonstrate that the food is bioengineered, or do not demonstrate whether the food is bioengineered, the symbol disclosure must be the following:

Figure 1 to § 66.104

(c) The symbol may be printed in black and white.

(d) Nothing can be added to or removed from the bioengineered food symbol design except as allowed in this part.

7 C.F.R. § 66.106

If a required bioengineered food disclosure is made through an electronic or digital link printed on the label, the disclosure must comply with the requirements described in this section.

(a) Accompanying statement.

(1) An electronic or digital disclosure must be accompanied by, and be placed directly above or below, this statement: "Scan here for more food information" or equivalent language that only reflects technological changes (e.g., "Scan anywhere on package for more food information" or "Scan icon for more food information").

(2) The electronic or digital disclosure must also be accompanied by a telephone number that will provide the bioengineered food disclosure to the consumer, regardless of the time of day. The telephone number instructions must be in close proximity to the digital link and the accompanying statement described in paragraph (a)(1) of this section, must indicate that calling the telephone number will provide more food information, and must be accompanied by the statement "Call [1–000–000–0000] for more food information."

(b) Product information page. When the electronic or digital link is accessed, the link must go directly to the product information page for display on the electronic or digital device. The product information page must comply with the requirements described in this paragraph (b).

(1) The product information page must be the first screen to appear on an electronic or digital device after the link is accessed as directed.

(2) The product information page must include a bioengineered food disclosure that is consistent with § 66.102 or § 66.104.

(3) The product information page must exclude marketing and promotional information.

(4) The electronic or digital link disclosure may not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers; however, if this information must be collected to carry out the purposes of this part, the information must be deleted immediately and not used for any other purpose.

7 C.F.R. § 66.108

The regulated entity must not charge a person any fee to access the bioengineered food information through text message and must comply with the requirements described in this section.

(a) The label must include this statement "Text [command word] to [number] for bioengineered food information." The number must be a number, including a short code, that sends an immediate response to the consumer's mobile device.

(b) The response must be a one-time response and the only information in the response must be the appropriate bioengineered food disclosure described in § 66.102 or § 66.116.

(c) The response must exclude marketing and promotional information.

(d) A regulated entity that selects the text message option must comply with the requirements of this paragraph (d).

(1) The regulated entity must not collect, analyze, or sell any personally identifiable information about consumers or the devices of consumers.

(2) The regulated entity must not use any information related to the text message option for any marketing purposes.

(3) If any information must be collected to carry out the purposes of this part, the information must be deleted as soon as possible and not be used for any other purpose.

7 C.F.R. § 66.109

Notwithstanding any provision in this subpart, if a food manufacturer (other than a very small food manufacturer), a retailer, or an importer has actual knowledge that the food is a bioengineered food or contains a bioengineered food ingredient, it must disclose that the food is bioengineered or contains a bioengineered food ingredient, as applicable, using appropriate text, symbol, electronic or digital link disclosure, or text message.

7 C.F.R. § 66.116

(a) Disclosure of bioengineered food by exempt entities. If a food on the List of Bioengineered Foods is subject to disclosure, a very small food manufacturer, restaurant, or similar retail food establishment may voluntarily provide that disclosure. The disclosure must be in one or more of the forms described in this paragraph (a).

(1) A text disclosure, in accordance with § 66.102.

(2) A symbol disclosure, in accordance with § 66.104.

(3) An electronic or digital link disclosure, in accordance with § 66.106.

(4) A text message disclosure, in accordance with § 66.108.

(5) Appropriate small manufacturer and small and very small package disclosure options, in accordance with §§ 66.110 and 66.112.

(b) Disclosure of foods derived from bioengineering. For foods or food ingredients that do not meet paragraph (1) of the definition of bioengineered food in § 66.1, that do not qualify as a factor or condition under paragraph (2) of the definition of bioengineered food in § 66.1, that are not exempt from disclosure under § 66.5, and that are derived from a food on the List of Bioengineered Foods, regulated entities may disclose such foods with one of the disclosures described in this paragraph (b).

(1) A text disclosure with the following statement: "derived from bioengineering" or "ingredient(s) derived from a bioengineered source." The word "ingredient(s)" may be replaced with the name of the specific crop(s) or food ingredient(s).

(2) A symbol disclosure using the following symbol:

Figure 1 to § 66.116

(3) An electronic or digital link disclosure, in accordance with § 66.106, provided that the disclosure is the text described in paragraph (b)(1) of this section or the

symbol in Figure 1 to this section.

(4) A text message disclosure, in accordance with § 66.108, provided that the response is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.

(5) Appropriate small manufacturer and small and very small package disclosure options, in accordance with §§ 66.110 and 66.112, provided that the disclosure is the text described in paragraph (b)(1) of this section or the symbol in Figure 1 to this section.

(c) Appearance of disclosure. The disclosure should be of sufficient size and clarity to appear prominently and conspicuously on the label, making it likely to be read and understood by the consumer under ordinary shopping conditions.

(d) Recordkeeping. Reasonable and customary records should be maintained to verify disclosures made under this section, in accordance with § 66.302.

7 C.F.R. § 66.118

Nothing in this subpart will prohibit regulated entities from making other claims regarding bioengineered foods, provided that such claims are consistent with applicable Federal law.